UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BAUSCH & LOMB INCORPORATED & PF | Civil Action No.: 20-cv-01463-GBW-CJB CONSUMER HEALTHCARE 1 LLC

Plaintiffs,

vs.

SBH HOLDINGS LLC,

Defendant

OBJECTION TO MAGISTRATE JUDGE BURKE'S MEMORANDUM ORDER DATED FEBRUARY 24, 2025 (D.I. 259)

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Defendant objects to Magistrate Judge Burke's January 10, 2025 Memorandum Order (D.I. 259) excluding the opinions and any testimony of Defendant's expert, Dr. Mathew Kaser. *Inter alia*, Dr. Kaser has a PhD in biochemistry from Oxford University and is a registered and practicing patent agent. (D.I. 166, ex. 6). The order excluded Dr. Kaser as an expert solely on the basis that he is unqualified under the **disputed** definition of the POSITA.

Judge Burke erroneously, without any admissible evidence, **construed** the **unverified** POSITA definition proposed by plaintiffs in a manner such that Dr. Kaser did not meet the disputed definition. In so doing, Judge Burke ignored Dr. Kaser's verified understanding of the proposed definition and also ignored the well-established rule of construction, the "rule of the last antecedent". Judge Burke wrongly made factual determinations as to what constitutes a POSITA, a matter reserved to the jury. In excluding Dr. Kaser, the order wrongly deprives the jury the aid of his expertise, as a biochemist, in the central area of his testimony – the physiological effect of vitamin C on the human eye. Also, Judge Burke failed to even deal with Dr. Kaser's other expert opinions, based upon his being a long-time active patent agent, that prosecution history estoppel bars Plaintiffs' claim for infringement under the doctrine of equivalents. Further, Judge Burke failed to address Dr. Kaser's opinion about non-infringing competitors. In sum, the order excluding Dr. Kaser's opinions and testimony is clearly erroneous, and unduly prejudicial to the Defendant. Thus, Plaintiffs' Daubert motion must be denied.

I. STANDARD OF REVIEW

In reviewing a Magistrate's order on a non-dispositive matter, "the Court will review any factual findings for clear error," and "legal conclusions [] will be reviewed de novo." *Cornell Univ. v. Illumina, Inc.*, 2017 WL 89165, at *8 (D. Del. Jan. 10, 2017). The Court must set aside or modify the Order if it is "clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a). Here, Judge Burke committed clear error and his order is contrary to law.

II. ISSUES

Plaintiffs' patents claim about 600 mg of vitamin C. The issue concerns Dr. Kaser's expert qualifications to testify about the effect on the human eye of vitamin C in excess of 600 mg. Dr. Kaser opines that the increased amount of 750 mg of vitamin C has a significant physiological effect on the human eye, disagreeing with Plaintiffs' expert. Underlying the granting of the motion was Judge Burke's acceptance of an **unverified** interpretation of the POSITA proffered by Plaintiffs, with which interpretation Dr. Kaser disagreed in his submitted declaration. (D.I. 204). Dr. Kaser's understanding was that he, with a PhD in biochemistry, qualified as a POSITA. *Id.* Moreover, Plaintiffs' expert agreed with Dr. Kaser's understanding in prior trial testimony concerning the same patents and same definition of POSITA tendered here. Plaintiffs' expert testified that POSITA could be "someone with a master's or Ph.D. nutrition, chemistry, biochemistry or related disciplines." (See Ex. 1, hereto).

Further because Judge Burke disqualified Dr. Kaser on POSITA grounds, Judge Burke did not address the other areas of Dr. Kaser's expertise and opinions regarding

prosecution estoppel, vitiation, ensnarement, and non-infringing alternative. (D.I. 259,pp2-3). Because as set forth below, Dr. Kaser was improperly excluded on the general basis that he is not a POSITA, it follows that Judge Burke erred in excluding Dr. Kaser's other opinions.

III. **ARGUMENT**

A. AT A MINIMUM THERE IS NO AGREEMENT AS TO THE DEFINITION OF A POSITA AND THUS IT IS A JURY ISSUE

It is undeniable there is a dispute as to the definition of POSITA. (D.I. 259 p.5) When there are disputes over the qualification of an expert that has credentials that are relevant to the subject matter at issue, caselaw holds that an expert can be qualified. Seb S.A. v. Montgomery Ward & Co., Inc., 594 F.3d 1360,1373 (Fed. Cir. 2010); See Also DraftKings Inc. v. AG 18, LLC, IPR2022-01447, Patent 9,613,498 B2 (P.T.A.B Mar 13, 2024):

"Although Dr. Lane does not have experience in gambling games per se, we note that there need not be a perfect match between the expert's qualifications and the patent at issue. See SEB S.A. v. Montgomery Ward & Co., [citation omitted] It is not necessary for Dr. Lane to demonstrate that he is an expert in poker or any specific wager-based games. Indeed, to testify as an expert under Fed. Rule Evid. 702, a person need not be one of ordinary skill, but may be "qualified in the pertinent art."

Thus, Dr. Kaser's PhD in biochemistry is sufficient to qualify him regardless of whether he qualifies under Judge Burke's chosen definition of a POSITA. It is up to the jury to evaluate the strength of his POSITA qualifications.

Contrary to the foregoing law, Judge Burke simply favored an interpretation tendered by Plaintiffs without any verification from Plaintiffs' expert as to what she meant by her definition. Even if her definition were to coincide with the interpretation given to it by Plaintiffs, it does not conform to how Dr. Kaser understood it, a fact attested to by his declaration. (D.I. 204). At the very least there is a triable issue of fact as to what constitutes a POSITA.

B. JUDGE BURKE ERRED IN HIS CONSTRUCTION OF THE PROPOSED DEFINITION OF A POSITA

Assuming arguendo it was proper for Judge Burke to engage in construing the meaning of the proffered POSITA definition, Judge Burke's decision is also contrary to normal rules of construction of a writing. He failed to apply the "rule of the last antecedent". *Lockhart v. United States*, 577 U.S. 347, 351-52 (2016). As noted by the Supreme Court, in applying the last rule of the antecedent, that rule commands "that a limiting clause or phrase should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Id.* Applying the rule of last antecedent here, the limiting clause or phrase is "and experience in the nutritional supplement area,". This phrase applies to the last antecedent noun, "discipline". (D.I. 259, pp. 4-5). Dr. Kaser cannot be faulted for following the normal rules of construction, which comport with his understanding as he stated in his declaration. (D.I. 204). Dr. Kaser's understanding was that a qualifying phrase of "and experience in the nutritional supplement area,..." applied to "a related discipline" not to a biochemist PhD. (D.I. 204).

Not only did Dr. Kaser interpret himself as a POSITA because he had a PhD in biochemistry, this is exactly as Plaintiff's expert testified at prior trial as to these very same patents at issue here. That expert, Dr. Johnson, testified as follows:

Q. I know you've testified earlier about your definition of it, but could you just remind the jury what your definition of a person of ordinary skill in the art is?

A. Sure. That would be someone who is a physician or an

optometrist or someone with a master's or Ph.D. in nutrition, biology, chemistry, biochemistry or related discipline.

Bausch & Lomb vs. Vitamin Health 13-cv-6498 (WDNY 8/4/16) DI 361 pp16-17, Ex. 1 hereto.

On one hand, Judge Burke had a **verified** (and logical) definition of POSITA by Dr. Kaser. On the other hand, he had an **unverified** definition submitted by Plaintiffs. Thus, on that record alone there was no evidentiary basis for Judge Burke's erroneous choosing one definition over another. This is particularly true because the ostensible "author" of the unverified definition Plaintiffs testified under oath that her definition means as Dr. Kaser understood it, i.e.an individual such as himself with a PhD in biochemistry qualifies as a POSITA.

C. THE THIRD CIRCUIT HAS LIBERAL STANDARDS FOR THE ADMISSIBILITY OF EXPERT TESTIMONY ON **OUALIFICATIONS**

The Federal Circuit reviews the admissibility of expert testimony under the law of the regional circuit. Sport Dimension, Inc. v. Coleman Co., 820 F.3d 1316, 1323 (Fed. Cir. 2016). Micro Chem., Inc. v. Lextron, Inc., 317 F.3d 1387, 1391 (Fed. Cir. 2003). Thus, Third Circuit standards apply here.

In the Third Circuit, an expert is qualified if the witness has specialized expertise to aid the trier of fact. Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003). In 360Heros, Inc. v. GoPro, Inc., 569 F. Supp. 3d 198, 201-202 (D. Del. 2021), this Court outlined the Third Circuit standard for admissibility of expert testimony based on qualifications as follows:

'Third Circuit interprets the "qualifications" requirement liberally, and has observed that "a broad range of knowledge, skills, and training qualify an expert as such." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994)'

'On this score, the Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications." Paoli II 741. (emphasis added) The requirement that a witness must possess "specialized knowledge" of the area of testimony is to be interpreted "liberally," but "at a minimum, a proffered expert witness ... must possess skill or knowledge greater than the average layman." Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998). [Emphasis added].

Under Third Circuit law, Dr. Kaser has the requisite knowledge, skills, and training as an expert and thus qualified.

D. KYOCERA IS INOPPOSITE AND NOT PRECEDENTIAL IN THE THIRD CIRCUIT

Judge Burke relied upon Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n, 22 F.4th 1369, 1376-77 (Fed. Cir.2022). First, this is a dubious precedent as a matter of law, for as noted above, the district court must apply the law of the Third Circuit. See *Treehouse* Avatar LLC v. Valve Corp., 54 F.4th 709, 713 (Fed. Cir. 2022) ("The grant or denial of motions to strike an expert report is not an issue unique to patent law. As such, we review such issues under the law of the applicable regional circuit."); see also Sport Dimension, Inc. v. Coleman Co., supra.

Even if applied here, Kyocera is inapposite. In Kyocera, the expert witness admittedly did not meet any of the **agreed** qualifications of a POSITA. Kyocera at 1377. Here, there is manifestly no agreed definition as to Plaintiffs' proposed interpretation of the proposed POSITA definition. As noted above, Judge Burke erroneously chose a definition contrary to the verified evidence before him and contrary to rules of construction. The issue of the definition of POSITA should have been reserved for jury determination.

It is virtually undeniable, and certainly logical that a biochemist with a PhD is a person qualified on the issue of the physiological impact of an increased amount of vitamin C on the human eye. It is testimony to this issue that an expert properly testifies about to aid the jury under FRE 702. Here, Dr. Kaser does **not** serve "...only to cause mischief and confuse the factfinder...." *Kyocera at* 1377. His testimony does **not** "...amount[] to ...[anything]...more than advocacy from the witness stand...." *Id.* He is not presenting junk science.

E. THE COURT ERRED AS KASER SATISFIED PLAINTIFFS' AND THE COURT'S OWN DEFINITION OF A POSITA

Here, unlike the expert in *Kyocera*, Dr. Kaser is undeniably competent to address the tendered vitamin C issue regardless of any agreed definition of POSITA. Dr. Kaser meets the proper definition of a **pertinent** expert for this case.

The reason Judge Burke excluded Dr. Kaser is because Judge Burke, contrary to the only verified evidence before him, decided being a biochemist was not enough. Aside from his choosing a disputed definition of POSITA, his position makes no sense since nowhere does Judge Burke determine that Dr. Kaser lacks the qualification to testify as to the issue of the effect of Vitamin C on the eye. This contrasts to *Kyocera*, *supra*, where that court found: "Here, Dr. Pratt does not have ordinary skill in the art. The level of ordinary skill in the art, adopted during claim construction, requires experience in power nailer design. And Dr. Pratt lacks such experience." *Id.* Thus unlike in *Kyocera*, Judge Burke did not have before him an agreed definition of a POSITA; nor, unlike in *Kyocera* was there any concession that Dr. Kaser was not qualified as a POSITA. See *Kyocera* at 1377: "And Dr. Pratt lacks such experience. Kyocera does not challenge these findings on appeal."

F. THE COURT ERRED AS KASER QUALIFIES AS A EXPERT REGARDLESS OF THE DEFINITION OF A POSITA

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Here, as noted above, Dr. Kaser's expert testimony goes to what effect increasing the amount of vitamin C above Plaintiffs' claimed amount has on the eye. This presents a narrow issue as to whether he is competent to testify to that. Thus, regardless of whether he is skilled in the art, per any definition, is immaterial to his testimony on this narrow topic. There is no argument that his expert testimony is scientifically based and relevant. See Mercedes-Benz v. Coast Automotive, 362 F. App'x 332, 334 (3d Cir. 2010):

"Under Federal Rule of Evidence 702, expert testimony must be both reliable and relevant to be admitted. A reliable opinion is "based on 'the methods and procedures of science' rather than on 'subjective belief or unsupported speculation." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994) (citing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 590, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

In sum, Dr. Kaser's opinions, as a PhD in biochemistry will "assist the trier of fact." (Fed.R.Evid. 702).

G. THE COURT ERRED BY FINDING DR. KASER WAS NOT **OUALIFIED AS DR. KASER'S QUALIFICATIONS FIT THE** ALTERNAIVE PRONG OF THE PROFFERED POSITA **DEFINITION.**

Assuming arguendo that the definition of POSITA adopted by Judge Burke were to be applied here, Dr. Kaser meets the alternate conditions stated therein:

Alternatively, a POS[IT]A at the time could have been a person with a Bachelor's degree with a greater number of years of experience.

or

The POS[IT]A would have, or would have access to, general information regarding AMD, the convenience and needs of patients who suffer from AMD, and background information. (D.I. 259, p.5).

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As to both prongs of the alternative definition (above), Dr. Kaser has the requisite minimum of a Bachelor's degree with a "greater number of years of experience" (D.I 166, Ex. 6, pp. 3-4 and ex. 1 thereto) and Dr. Kaser clearly had or would have had access to "general information regarding AMD". (D.I 166, Ex. 6, pp. 3-4 and ex. 1 thereto)

IV. **CONCLUSION**

Defendant, in view of the foregoing arguments, requests that the Court deny Plaintiffs' Daubert motion to disqualify Dr. Kaser.

Respectfully Submitted,

/s/ Glenn A. Brown

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CERTIFICATION OF OBJECTIONS

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The foregoing objections raise no new legal/factual arguments, only expounding on legal and factual arguments presented in the Defendant's Opposition Brief, with the exceptions that Defendant augments the factual argument of how Dr. Kaser's understanding of the proffered POSITA corresponds to the language thereof by submitting the testimony of Plaintiffs' expert in

Bausch & Lomb vs. Vitamin Health 13-cv-6498 (WDNY 8/4/16) DI 361 pp16-17, Ex. 1 hereto.

As to this, good cause exists to consider such because the facts were known to Plaintiffs because it involved testimony elicited by Plaintiffs' counsel herein, Steve Kline, and pertains to the same patents at issue herein and testimony about the POSITA definition by the same expert witness herein, Dr. Johnson.

Defendant also cites case law re the "rule of the last antecedent". Lockhart v. United States, 577 U.S. 347, 351-52 (2016) which legally supports and augments the argument made about Dr. Kaser's understanding of the proffered POSITA definition. Good cause for this citation is because only became apparent given the issued Order in which Judge Burke engages in an interpretation analysis that Defendant contents is at odds with said rule.

/s/Glenn A.Brown

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